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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,615	12/04/2003	Vivek M. Rangnekar	028750-225	5759

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,615	RANGNEKAR, VIVEK M.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are pending in this application and subject to restriction. Claim 11 recites "the method of claim 9", however, claim 9 is drawn to an antibody and claim 16 recites "the kit of claim 14", however claim 14 does not provide proper antecedent basis for a first antibody. Claim 24 recites "the amino acid sequence of claim 3" but claim 3 is not drawn to an amino acid sequence. For purposes of establishing restriction groups, the dependency of claim 11 is assumed to be from claim 10,which is drawn to a method and the dependency of claim 16 is assumed to be from claim 15, which is drawn to a kit comprising "a second antibody" and the dependency of claim 24 is assumed to be from claim 1, which is drawn to an amino acid sequence.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 6 and 24, drawn to a modified Par-4 protein, classified in class 530, subclass 350.

II. Claims 3-5, 13 and 14, drawn to an isolated nucleic acid construct comprising 500 contiguous including a polymorphic site, classified in class 435, subclass 320.1.

III. Claims 7 and 8, drawn to a method of producing a polypeptide, classified in class 435, subclass 69.1.

IV. Claims 9, 15, 16 and 17, drawn to an antibody or kits comprising the antibody, classified in class 530, subclass 387.9.

V. Claims 10 and 11, drawn to a method of screening for test compounds that bind to target polypeptide sequences, classified in class 435, subclass 7.1.

VI. Claim 12, drawn to a therapeutic compound comprising an agent that binds to the nucleic acid, agent is unknown thus it cannot be classified.

VII. Claim 12, drawn to a therapeutic compound comprising an agent that binds to the polypeptide sequence, agent is unknown thus it cannot be classified.

VIII. Claims 18-23, drawn to a method of treating cancer comprising administration of a Par-4 mutant, classified in class 514, subclass 2.

The inventions are distinct each from the other because of the following reasons:

Inventions of Group I and Group II are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are related in that the nucleic acid of Group II *can* encode a polypeptide of Group I. However, Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a nucleic acid of group II does not necessarily encode a protein of group I. Furthermore, the information provided by the nucleic acid of group

II can be used to make a materially different protein than that of group I. In addition, while a polypeptide of group I can made by methods using some, but not all, of the polynucleotides that fall within the scope of group II, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated from a non-recombinant cell using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups I and II together.

Inventions of Group I and Group IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed

are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed both are polypeptides. While the inventions of both group I and group IV are polypeptides, in this instance the polypeptide of group I is a single chain molecule that functions as a pro-apoptotic protein whereas the polypeptide of group IV encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group IV are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group IV is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Furthermore, searching the inventions of group I and group IV would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody, which binds to the polypeptide, require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group IV. Furthermore, antibodies, which bind to an epitope of a polypeptide of group, I may be known even if a polypeptide of group II is novel. In addition, the technical literature search for the polypeptide of group II and the antibody of group

III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

Inventions of Group III and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide can be made by chemical synthesis or isolated from a cell that produces it naturally.

Searching the inventions of either of Groups I and III together would impose serious search burden. The inventions of Groups I and III have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptide and the method of making the peptide are not coextensive. Prior art, which teaches a polypeptide, would not necessarily be applicable to the method of making the polypeptide. Moreover, even if the product were known, the method of making the product may be novel and unobvious in view of the preamble or active steps.

Inventions of Group I and either Group V or VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be used to produce antibodies, or either of the methods of Groups V and VIII.

Searching the inventions of Group I and Group V or VIII together would impose serious search burden. The inventions of Groups I and V or VIII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptide and the method of using the polypeptide are not coextensive. Prior art, which teaches a polypeptide, would not necessarily be applicable to the method of using the polypeptide. Moreover, even if the product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions of any of Groups I, II, IV versus either of groups VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the compositions of Groups VI and VII are unknown as they have yet to be identified whereas the products or Groups I, II and IV are known and isolated.

Inventions of Group II and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid can be used as probes to identify related genes or clones.

Searching the inventions of Groups II and III together would impose serious search burden. The inventions of Groups II and III have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the nucleic acid and the method of using the nucleic acid are not coextensive. Prior art, which teaches a nucleic acid,

would not necessarily be applicable to the method of using the nucleic acid. Moreover, even if the product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions of Group II and Group IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are related as the nucleic acid can encode a protein recognized by the antibody. However, the nucleic acid of group II and the antibody of group IV are patentably distinct for the following reasons. The antibody of group IV includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group IV which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a nucleic acid of group II will not encode an antibody of group IV, and the antibody of group IV cannot be encoded by a polynucleotide of group II. Therefore the antibody and polynucleotide are patentably distinct. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group IV would impose a serious search burden since a search of the nucleic acid of group II is would not be used to determine the patentability of an antibody of group IV, and vice-versa.

Inventions of Group II and either Group V or Group VIII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the nucleic acid of Group II is neither made by or used in the method of screening for therapeutic agents of Group V or the method of treating cancer of Group VIII.

Inventions of Group IV and either Groups III, V or VIII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antibody of Group IV is neither made by or used in the method of producing a polypeptide of Group III. As set forth above, the polypeptide produced by the method of Group IV is structurally and functionally distinct from the antibody of Group III. As such the antibody is not used in or made by the methods of Group III, V or VIII.

Inventions of Group VI and either Groups III, V or VIII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the therapeutic compositions of Group VI is neither made by or used in the method of producing a polypeptide of Group III, a method of screening using a polypeptide or a method of treating cancer of Group VIII, which uses the Par-4 polypeptide.

Inventions of Group VII and either Groups III or VIII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the therapeutic compositions of Group VII is neither made by or used in the method of producing a polypeptide of Group III or a method of treating cancer of Group VIII, which uses the Par-4 polypeptide.

Inventions of Group VII and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition can be used to treat cancer, and, as a screen, the method also uses compounds that do not bind to the polypeptide.

Searching the inventions of Group VII and Group V together would impose serious search burden. The inventions of Groups V and VII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the composition and the method of using the composition are not coextensive. Prior art, which teaches the composition, would not necessarily be applicable to the method of using the composition. Moreover, even if the product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions of Groups III, V and VIII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are

either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods are related by use of Par-4 polypeptides and nucleic acids. However, the methods of Groups III, V and VIII have distinct modes of operation. Group III is drawn to a method of using the nucleic acid to encode a polypeptide while the method of Group V is drawn to methods of using the polypeptide to screen for therapeutic compounds and the method of Group VIII is drawn to a method of treating cancer using the polypeptide. The method of Group III uses method steps and materials that are not required of Groups V and VIII such as operatively linking the sequence to a promoter and deliverance into a cell for protein expression. The method of Group VIII uses method steps and material that are not required of Group V such as preparation of the polypeptide for *in vivo* use as well as steps of *in vivo* administration.

Furthermore, the distinct steps and products require separate and distinct searches. A search for art pertaining to methods of using a polypeptide is distinct from a search for art pertaining to methods of making a polypeptide. As well, a search for art for screening methods is distinct from methods of treating cancer. As such, it would be burdensome to search the inventions of Groups III, V and VIII together.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101,

103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai, In re Brouwer* and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Examiner
Art Unit 1633

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER